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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/018,451

03/07/2002

Ernst Bernhard Grabitz

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ABELMAN, FRAYNE & SCHWAB
666 Third Avenue
New York, NY 10017-5621

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/018,451	Applicant(s) GRABITZ, ERNST BERNHARD	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 and 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 11 September 2006 after a Final action mailed 10 March 2006. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 10 March 2006 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed on 11 September 2006 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Applicant's Preliminary Amendment filed 25 September 2006 is acknowledged and entered.
3. Applicant's responsive Amendments filed 11 and 25 September 2006 are acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.
4. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/018,451), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.
5. In view of amendments and remarks filed 11 and 25 September 2006 following objections in Office Action mailed 10 March 2006 are hereby withdrawn:
 - The objection to Claims 50, 58-60 and 64-70.
6. In view of amendments and remarks filed 11 and 25 September 2006 following objections in Office Action mailed 10 March 2006 are herewith withdrawn:
 - Indefiniteness of recited claimed invention to Claims 50-70 under 35 U.S.C. §112, second paragraph;

- Obviousness rejection to Claims 50-70 under 35 U.S.C. § 103 (a) as obvious over combined teachings from Pannell (U.S. Patent 5,288,632 A), in view of Sagar et al (WO 94/22572).

Claim Status

7. Claims 1-49 remain cancelled.
8. Claims 66-70 have been amended.
9. Claims 50-70 are pending.

Objection To Claims – Minor Informalities

10. Claims 50-65 are objected to because of the following informalities:
 - Subject matter claimed in Claim 50 will be more clearly understood by replacing the word containing at Line 2 with the phrase, --wherein said cell wall contains--;
 - At claim 51, Line 3; the phrase, “external cell membrane of the microorganism” is confusing because depending on the microorganism, the outer membrane will be either the art-known terminology plasma membrane or plasmalemma, or the outermost layer of the cell wall because the latter is also a fully integrated structure. Note that the word microorganism encompasses any organism invisible to naked eye;
 - At Claim 58, Line 3, after the word “substance. inserting the phrase, --that is-- will further clarify said claim;
 - At Claim 62, Line 3, writing the phrase, “0.025 M” before the phrase, “sodium citrate” will further clarify said claim;
 - At Claim 63, Line 2, writing the phrase, “0.025 M” before the phrase, “sodium citrate” will further clarify said claim;

- At Claim 64, Line 1, writing the “,” after the number, “50” and deleting the “,” after the word, “wherein” will further clarify said claim.
- Appropriate correction is required.

Claim Rejections - 35 U.S.C. §112

First Paragraph Rejections

11. Claims 50-70 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession; at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

The factors considered in the Written Description requirement are: (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." (MPEP §2163).

In the instant case, the claims are drawn to a method comprising a variety of steps to prepare a composition; and a composition, wherein a microorganism's cell wall is prepared by treating said microorganism with a hypertonic solution and subsequent to centrifugation to separate the mixture of cell wall with oozed out intracellular materials, the prepared cell wall is loaded with "one or more pharmacological or nutritional substances", wherein said "substances are soluble in an aqueous solution". Additional claims are drawn to specific pharmaceutical and nutritional substances/salts/ materials, wherein said specific pharmaceutical and nutritional substances/salts/ materials "are soluble in an aqueous solution".

The claimed invention is assessed as follows with regard to the written description factors listed *supra*.

(a) Level of skill and knowledge in the art:

At least a Bachelor Degree in Biochemical engineering, Biochemistry, Biology, Biophysics, Chemical engineering, Chemistry, Enzymology, Microbiology, Molecular biology, Protein Chemistry, or Proteomics.

(b) Partial structure:

The partial structure of the claimed product prepared according to the claimed process method steps as exemplified for *Saccharomyces cerevisiae* cell wall have been adequately presented.

(c) Physical and/or chemical properties:

The physical and chemical properties of the claimed product prepared according to the claimed process method steps as exemplified for *Saccharomyces cerevisiae* cell wall have been adequately presented to assess the nature of the claimed product prepared according to claimed method.

(d) Functional characteristics:

In the specification as currently presented, the structure-function relationships and functional effects of any or all of the microorganism cell walls and different cell wall

preparations comprising some of the claimed pharmaceutical and nutritional substances/chemicals have been described for only the *Saccharomyces cerevisiae* cell wall preparations according to recited Claims that embody the claimed invention. The specification, however, only mentions the selection criteria for suitable microorganisms and among other microorganisms specifically mentions *Baillus subtilis* and *Lactobacillus* spp. An artisan of skill will not be apprised to practice the claimed invention with a variety of other microorganisms that also have cell walls and are also common to gastrointestinal tract, e.g., spores of filamentous fungi, unicellular protozoa and cysts.

(e) Method of making the claimed invention:

From the record of the present written disclosure, the specification (Specification, Examples 1-11) presents a detailed and comprehensive methodology to prepare claimed product with only *Saccharomyces cerevisiae* cell walls, let alone other yeasts (e.g., *Debaryomyces* spp., *Hansenula* spp., *Kluyveromyces* spp., *Pichia* spp., *Schizosaccharomyces* spp., or *Zygosaccharomyces* spp. to name a few) **Thus, the claimed invention in absence of a clear and succinctly evidenced method of making said invention with any or all microorganisms is considered to those stated at various places (e.g., Pages 5-50) in the specification as currently presented. This is because of the absence of demonstrated evidence of record that said method would be applicable to each and every species claimed in the broad genus of microorganisms.**

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claims because Claim 1 is the generic claim, and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

12. Claims 50-70 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method (i.e., Claims 50-65) and a preparation, i.e., composition (Claims 66-70) prepared according to product-by-process claims. More specifically, the claims are drawn to a method comprising a variety of steps to prepare a composition; and a composition, wherein a microorganism's cell wall is prepared by treating said microorganism with a hypertonic solution and subsequent to centrifugation to separate the mixture of cell wall with oozed out intracellular materials, the prepared cell wall is loaded with "one or more pharmacological or nutritional substances", wherein said "substances are soluble in an aqueous solution". Additional claims are drawn to specific pharmaceutical and nutritional substances/salts/ materials, wherein said specific pharmaceutical and nutritional substances/salts/ materials "are soluble in an aqueous solution".

From the record of the present disclosure, however, the specification according to the currently presented description does not enable an artisan of skill to practice the invention with any or every microorganism as claimed for the following reasons:

- the claimed invention in absence of a clear and succinctly evidenced method of making said preparation with the broad genus of microorganisms;
- in the absence of demonstrated evidence of record that said method comprising said steps for any or all microorganisms does not evidence the applicability of said method for all microorganisms (e .g., fungal spores, cultured plant cells, protozoa) let alone all yeasts.

A person of ordinary skill would not be able to practice the invention because undue experimentation will be required to obtain a method to prepare cell walls from the broad genus of any or all microorganisms as claimed in the instantly presented Claims 50-65, and a composition comprising said walls as claimed in instantly presented claims 66-70 due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as illustrated below.

a. Quantity of Necessary Experimentation

The specification as currently presented, besides giving an extensive description with only the *Saccharomyces cerevisiae*, not even other yeasts (e.g., *Debaryomyces* spp., *Hansenula* spp., *Kluyveromyces* spp., *Pichia* spp., *Schizosaccharomyces* spp., or *Zygosaccharomyces* spp.) as illustrated above; does not provide any evidence on how the claimed inventive method would indeed be applicable to any or all microorganisms, or groups of microorganism having a cell wall. Thus, any and each microorganism to be suitable for the claimed invention will have to be tested individually to at least ascribe groups of microorganisms suitable for practicing the claimed invention.

b. Limited Amount of Guidance

The specification as currently presented does not provide a clear-cut guidance to practice the claimed invention with the broad genus encompassing any or all microorganisms.

c. Limited Number of Working Examples in the Specification

The specification or the claims as currently presented do not clearly define all the embodiments for any or all microorganisms.

d. Nature of the Invention

The invention is unclearly defined and is not concise and clear.

e. State of the Prior Art

Despite a lengthy discussion on the prior art, the specification provides only one evidence where commercially available *Saccharomyces cerevisiae* cells are applicable for the claimed invention.

f. Relative Skill Level of those in the Art

At least a Bachelor Degree in Biochemical engineering, Biochemistry, Biology, Biophysics, Chemical engineering, Chemistry, Enzymology, Microbiology, Molecular biology, Protein Chemistry, or Proteomics.

g. Predictability or Unpredictability in the Art

Unless supported with illustrative experimental evidence, biological responses are unpredictable. Thus, information obtained under one set of detrimental parameters may not be extrapolated for another set of parameters/environmental or specific conditions.

h. Breadth of the Claims

The claimed invention is drawn upon claims that are not supported by the presently detailed specification.

13. Claims 50-70 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims.

The claims are drawn to a method (i.e., Claims 50-65) and a preparation, i.e., composition (Claims 66-70) prepared according to product-by-process claims. More specifically, the claims are drawn to a method comprising a variety of steps to prepare a composition; and a composition, wherein a microorganism's cell wall is prepared by treating said microorganism with a hypertonic solution and subsequent to centrifugation to separate the mixture of cell wall with oozed out intracellular materials, the prepared cell wall is loaded with "one or more pharmacological or nutritional substances", wherein said "substances are soluble in an aqueous solution". Additional claims are drawn to specific pharmaceutical and nutritional substances/salts/ materials, wherein said specific pharmaceutical and nutritional substances/salts/ materials "are soluble in an aqueous solution".

From the record of the present disclosure, however, the specification according to the currently presented description does not enable an artisan of skill to practice the invention with any or every microorganism as claimed for the following reasons:

- the claimed invention in absence of a clear and succinctly evidenced method of making said preparation with the broad genus of microorganisms;
- in the absence of demonstrated evidence of record that said method comprising said steps for any or all microorganisms does not evidence the applicability of said method

for all microorganisms (e.g., fungal spores, cultured plant cells, protozoa) let alone all yeasts.

A person of ordinary skill would not be able to practice the invention because undue experimentation will be required to obtain a method to prepare cell walls from the broad genus of any or all microorganisms as claimed in the instantly presented Claims 50-65, and a composition comprising said walls as claimed in instantly presented claims 66-70 due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as illustrated above.


Conclusion

14. For aforementioned reasons, no Claims are allowed.
15. Please note that Applicant's Representative was presented with a proposed Examiner's Amendment to bring the claims of record in a better condition for allowance. In a telephone conversation on 12/26/2006, Applicant's Representative advised the Examiner that said Examiner's Proposed Amendment was not acceptable to applicant.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kallash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

February 5, 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/1657